User guide:

Report of Adverse Event Following Immunization (AEFI)

Version 1.0

To be used as a guide for completion of:
The New Brunswick Adverse Event Following Immunization reporting form

November 2010

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Frequently Used Acronyms

AEFI	Adverse Event Following Immunization
AESI	Adverse Event of Special Importance
BGTD	Biologic and Genetic Therapies Directorate
CAEFISS	Canadian Adverse Effects Following Immunization Surveillance System
CDC	Communicable disease control
CIC	Canadian Immunization Committee
CIRID	Centre for Immunization and Respiratory Infectious Disease
CHN	Community health nurse
CSDS	Client Service Delivery System
GNB	Government of New Brunswick
GBS	Guillain Barré syndrome
GP	General practitioner
HCP	Healthcare professional
HPFB	Health Products and Food Branch
HPFBI	Health Products and Food Branch Inspectorate
IC	Immunization coordinator
MOH	Medical Officer of Health
MD	Medical doctor
NB	New Brunswick
NP	Nurse practitioner
OCMOH	Office of the Chief Medical Officer of Health
PH	Public Health
PHAC	Public Health Agency of Canada
PHO	Public Health office
PHN	Public Health nurse
RN	Registered nurse
SAEFI	Serious Adverse Event Following Immunization
SOP	Standard Operating Procedure
WHO	World Health Organization

1 GENERAL OVERVIEW

This guide is intended to be used when completing the report of Adverse Event Following Immunization (AEFI) for submission to New Brunswick (NB) Department of Health, local Public Health Offices and Public Health Agency of Canada (PHAC). The purpose of this guide is to help healthcare professionals (HCPs) complete the form accurately. It is not intended to guide the clinical assessment or management of the AEFI case.

What is AEFI surveillance?
AEFI surveillance (also known as vaccine safety surveillance) is a system designed to collect adverse events temporally associated with receipt of vaccines. This type of surveillance typically relies on health professionals associating an adverse event in an individual as a possible consequence of vaccination and reporting it to the appropriate authority.

Why AEFIs need to be reported?

- To ensure that the vaccines used in Canada are safe
- To maintain public confidence in Canada's immunization programs
- It is a health care professional responsibility
- It is a legal requirement in NB

What is done with AEFI reports at the provincial level?
The AEFI data are analyzed and disseminated at the provincial level to provincial stakeholders. Data are then sent to the PHAC via fax, post or electronically.

What is done with AEFI reports at the national level?
Personnel at the PHAC screen all submitted reports, ensure they are entered into the Canadian Adverse Event Following Immunization (CAEFI) database and coded using standard international coding systems. Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Canadian data are periodically forwarded on to the World Health Organization (WHO) International Drug Monitoring Program in Uppsala, Sweden, where global data are analyzed for any evidence of safety concerns.

2 DEFINITIONS

Adverse Event Following Immunization (AEFI)
An AEFI is any untoward medical occurrence in a vaccinee that follows immunization and that does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be <u>any</u> unfavorable and/or unintended sign, abnormal laboratory finding, symptom or disease.

Vaccine pharmacovigilance
Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, prevention, and communication of adverse events following immunization, or of any other vaccine- or immunization-related issues.

Adverse Event versus Adverse Reaction

- An Adverse Event is a noxious and unintended response to a vaccine that occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease.

- An Adverse Reaction, in contrast to an Adverse Event, is characterized by the fact that a causal relationship between the drug and the occurrence is suspected.

An AEFI can be classified as:

- Vaccine-induced event
  - Non-specific inflammatory responses (injection site reaction, fever)
  - Immune-mediated response (anaphylaxis)
  - Consequence of replication of microbial agents in vaccine (febrile rash)
  - Direct toxic effect of vaccine component or contaminant

- Vaccine potentiated event
  - Vasovagal response (syncope)
  - Hyperventilation
  - Stress-related

- Immunization error
  - Inappropriate transportation or storage
  - Failure to adhere to recommended schedule
  - Use of expired product or wrong diluents
  - Incorrect: dosage, injecting equipment, sterile technique, route or site of injection

- Other event
  - Infection
  - Reaction to concomitant medication
  - Response to environmental allergen or toxin
  - Manifestation of complication of birth injury or inherited condition
  - Trauma
  - Psychogenic illness

Serious AEFI* is an AEFI that:

- results in death;
- is life threatening;
- requires in-patient hospitalization or prolongation of an existing hospitalization;
- results in persistent or significant disability/incapacity;
- causes a congenital anomaly/birth defect;
- is medically important.

Life-threatening event* is an event/a reaction in which the client was at risk of death at the time of the event/reaction; it does not refer to an event/a reaction that hypothetically might have caused death if it were more severe.

- Example: anaphylaxis

Medically important events*:
Medical and scientific judgment should be exercised in deciding whether other situations should be considered as serious such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the client or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm or convulsions that do not result in hospitalization.

Unusual or unexpected AEFI
An event that is not identified in nature, severity, or frequency among the currently known adverse effects associated with the administration of the product. For example, first reports of intussusception following rotavirus immunization. Please refer to the current product information or labelling.

Serious AEFI versus Severe
The term "severe" is not synonymous with serious, and it is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe). The event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity), which is based on client/event outcome or action criteria, serves as guide for defining regulatory reporting obligations.

Medical Officer of Health (MOH) designate:
A designate is the healthcare professional who has the authority to complete the "recommendations for further immunization" such Public Health nurse (PHN) or immunization coordinator (IC).

Reportable event is an event that:
- meets the AEFI definition AND
- has a temporal association with a vaccine AND
- has no other clear cause at the time of reporting.

***** International Conference on Harmonization, Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting (ICH E2D) (2003).

3 REPORTING REQUIREMENTS

1. Trigger for reporting
Any adverse event that follows administration of an **active** immunizing agent (vaccine) should trigger the reporting. Each institution is responsible for ensuring that a process is in place to notify the individual who will be reporting.

NOTE: When an adverse event follows the administration of **passive** immunizing agent (e.g. immune globulin) and/or diagnostic agent (e.g. tuberculin skin test), an AEFI form should not be completed. Instead, the event should be reported to Health Canada on Canada Vigilance Adverse Reaction Reporting Form (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

2. Who can report
All HCPs in NB who administer vaccines and/or care for clients who may have had an AEFI are required by law to report the event to their local Public Health office (PHO) **within one week** of event identification.

3. What to report

Any reportable event should be forwarded to the local PHO.

NOTE: Expected non-serious AEFIs are not required to be reported, unless they are more severe or more frequent than expected.

- AEFI report should contain:
  - Client – unique identifier, date of birth and gender;
  - Immunization event(s) – province where given, date, all vaccines given including name, manufacturer, lot number, administration site and route, as well as the number in series of vaccine doses if relevant;
  - Adverse event(s) – description, including time of first onset following immunization, duration, health care utilization, treatment and outcome;
  - Relevant medical and treatment history – underlying disease, known allergies, prior AEFI, concomitant medication;
  - Associated event(s) – acute illness, injury, exposure to environmental toxins.
  - Reporter details.

4. **When to report**

- HCPs should notify their local PHO within **one week** of AEFI identification by telephone, post or fax
- If an AEFI was assessed as serious/requiring urgent medical attention/unusual or unexpected, an MOH should initially notify the Communicable disease control (CDC) unit within **one working day** by telephone, e-mail or fax, which should follow by a complete report within **one week**.
- The CDC unit will notify PHAC within **one week** of AEFI receipt.

NOTE: It is important to remember that **timeliness** of AEFI reporting is very important as it facilitates effective risk management and allows addressing any safety concerns quickly and efficiently. In the event of a matter that requires immediate attention (e.g. anaphylaxis reaction to a vaccine), the MOH should be informed as soon as possible by telephone after the client had received an appropriate treatment. This form should then be completed to document the event and sent to the CDC unit.

5. When an AEFI form needs to be completed:

In NB, an AEFI form should only be completed for reportable events that are:

- **serious** in nature; OR
- **required an urgent medical attention** (not resulting in hospitalization); OR
- **unusual / unexpected** (regardless of severity) .

NOTE: A casual relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality.

6. How to report:

- **Obtain the NB AEFI form**
  - Both the form and user guide are available on the Government of New Brunswick (GNB) website: www.gnb.ca
  - Or contact your local PHO for a copy

NOTE: the NB AEFI form supersedes that of the PHAC AEFI form and user guide available on the PHAC website.

- **More than one form can be completed for the same client under these circumstances:**
  - If the client has had more than one AEFI following vaccination(s) administered at different dates, then the separate AEFI details should be completed on separate forms.
  - If the client has had more than one AEFI following the vaccination(s) administered at the same time, then all AEFI details can be reported on the same form.

- **Minimal criteria for AEFI reporting to the MOH:**
  1. Client identification (ID) (name, date of birth and gender)
  2. Vaccine(s) received (name, date of administration, route, dose)
  3. Event description (onset, duration, symptoms, highest level of care)
  4. Reporter ID (name, contact information)

Lack of any of these four elements means that the report is incomplete.

- **Following MOH's review of the AEFI form:**
  - Transcribe all relevant to AEFI information into the AEFI module in Client Service Delivery System (CSDS)
    - NOTE: enter ALL AEFIs
  - Prior to sending AEFI-related documents to the CDC unit via fax, remove all confidential information in Section I in the form apart from:
    - First initial of client's first and last name
    - Date of birth
    - Gender
    - City/town
    - Postal code

4 INSTRUCTIONS FOR NB AEFI REPORTING FORM COMPLETION

Cover page

Please indicate what type of an AEFI is being reported on the form by ticking the appropriate category:

- Serious
- Required urgent medical attention
- Unusual or unexpected

Section 1: Provincial identifying info

Unique episode number
A unique case number is to be assigned to each AEFI report. This number will be assigned automatically if the AEFI form is completed electronically or will be assigned manually by the CDC unit for paper forms.

The format of this number: year/NB/Region N/ case number. The unique case number should be marked on the top of the 2nd, 3rd and 4th pages of the AEFI form as an identifier to link the pages together. If you are not authorized to assign this number, please leave this field blank.

Section 2: Client identification

Client Identification Information*:*

- First and last name;
- Provincial medicare number;
- Date of birth: Indicate the client's date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (*yyyy/mm/dd* format);
- Gender: Indicate client's gender (e.g., male or female).
- Address of usual residence including postal code (with the understanding that this address might be in a different province than where the vaccine(s) was administered or where the AEFI is being reported)
- Telephone number (either residential or business or both), where the client can be reached.

Information Source: If the source of the information for the AEFI report is a parent, or another care provider, provide the name, relation to the client and contact information (including the full mailing address and telephone number where he or she can be reached) if it is different from the client's.

Name of client's physician: Provide the name, mailing address and telephone number of client's family physician.

Section 3: Vaccine information

Provide all information pertaining to the immunizing agent(s) administered just prior to the onset of the reported AEFI(s). There is space to record three immunizing agents in this section;

however, if more than three were administered simultaneously, record the additional vaccines in Section 9.

Province of immunization: Record the province where the vaccine was administered (it could be different from the province of residency)

Date and time vaccine administered: Indicate the date and exact time of vaccine administration remembering to specify if the vaccine was administrated in the "a.m." or "p.m." by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g. month and/or year).

Immunizing agent(s): Please record the proper name or accepted abbreviation for all active immunizing agent(s).

- NOTE: if an active immunizing agent cannot be found in CSDS, please send an urgent request to the CDC unit and the agent will be added to the database.

***Trade name*:** Indicate the trade name of all vaccine(s) received.

Manufacturer: Specify the name of the manufacturer as indicated on the product label and as referenced in Appendix II.

Lot number: Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.

Dose number: Provide the number in series (1, 2, 3, 4 or 5) or indicate if known. For the Influenza vaccine, unless a client receives two doses in one season, the "dose #" should be recorded as one.

Dosage/unit: Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.

Route: Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable:

Intradermal: ID	Intramuscular: IM	Subcutaneous: SC
Intranasal: IN	Oral: PO	Other: please specify (no abbreviations)

Site: Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:

Left arm: LA	Right arm: RA	Arm: Arm	Left leg: LL	Right leg: RL
Leg: Leg	Left gluteal: LG	Right gluteal: RG	Gluteal: Glut	Mouth: Mo
Nose: Nose	Multiple sites: MS	Other: please specify (no abbreviations)		

Section 4: Immunization errors

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing "yes," "no" or "unknown". If "yes," please indicate all that apply

in Section 4 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in Section 9.

Given outside the recommended age limits: The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

Product expired: The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days; Vaxigrip expires within seven days of vial opening).

Dose exceeded that recommended for age: A larger dose of vaccine was administered than is recommended for the client's age group.

Wrong dose: Incorrect dose of vaccine was given

Wrong vaccine given: An unintended vaccine was administered.

Incorrect route**:** The vaccine was administered via an incorrect route of administration (e.g., subcutaneous vs. intramuscular).

Other: If an error has occurred that is not accurately reflected in the list of provided errors, please choose "other" and provide all details in Section 9.

Section 5: Previous AEFI

Indicate whether the client had ever experienced an AEFI following a previous dose of any of the immunizing agents as listed Section 3. Choose only one of the answers provided in Section 5, as described below:

No**:** The client had previously received immunization with one or more of the immunizing agents listed in Section 3 and had not experienced a subsequent AEFI.

Yes**:** The client had previously received immunization with at least one of the immunizing agents listed in Section 3 and had subsequently experienced an AEFI (any AEFI including expected and non-serious).

Unknown**:** It is unknown if the client had previously received immunization with any of the immunizing agents listed in Section 3 and/or, if an AEFI followed.

Not applicable**:** The client had never previously received immunization with any of the immunizing agents listed Section 3.

If the answer is "yes," the client had previously experienced an AEFI following a previous dose of one or more of the immunizing agent(s) listed in Section 3, provide all details of the previous AEFI in Section 9, including the corresponding time to onset and duration, when known. Also,

when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.

If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the client's past AEFI experience can be captured in Section 6), please provide additional details in Section 9.

Section 6: Level of care and outcome

Section 6a: Highest level of care obtained

Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in Section 6a, described in detail below.

Unknown: It is unknown if the client received care for the reported AEFI.

None: No care was received for the reported AEFI.

Telephone advice from a healthcare professional: The client received a telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI. This can also include a telephone advice from a provincial health information line such as Tele-Care (811).

Non-urgent visit: The client was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted in Section 9.

Emergency visit: The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted in Section 9.

Required hospitalization: Indicate if client was hospitalized for the assessment and/or treatment of the reported AEFI. If yes, provide the date of admission and the date of discharge. If a client was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all investigations conducted in Section 9.

Section 6b: Outcome at time of report

Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in Section 6b. If the client is not yet recovered, provide all available details in Section 9 and provide updates as they become available. Similarly, should the event result in permanent disability and/or incapacity or death, provide all available details in Section 9.

When completing Section 6b, provide the information as outlined below:

Death: Client died (record the corresponding date of death in the space provided).

Unknown: The outcome of the AEFI is unknown or unclear.

Not yet recovered: Residual signs and/or symptoms remain (at the time of the report).

Permanent disability/incapacity: An injury that impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.

Recovered: All signs and symptoms have resolved at the time of reporting. Please record the date in the space provided. If the reaction lasted >1 hour, but <1 day also provide the exact time of recovery.

Section 6c: Treatment received

Indicate whether the client received any treatment, including self treatment, for the reported AEFI by choosing "yes," "no" or "unknown". If "yes" was chosen, provide all details of treatments received, following the onset of the AEFI in the same section. Use Section 9 if more space is needed.

Section 6d: Medical history (up to the time of AEFI onset)

Indicate the client's medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details, when available, in the same section or in Section 9 if more space is needed. Enclose a print out if available.

Concomitant medication(s): Provide the name of all medications, including prescription, over the counter and herbal supplements that the client had been taking immediately prior to the time of AEFI onset, including those taken only as needed. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.

Known medical conditions/allergies: Indicate all known medical conditions and/or allergies that the client experienced prior to the time of immunization with a corresponding date of onset. If an exact date of onset is unknown, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.

Acute illness/injury: Indicate if the client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset).

Section 7: Reporter information

Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing

address of the institution/setting/centre. Indicate the setting in which the reporter is located (e.g., physician office, public health clinic, hospital, pharmacy) or specify if other.

Sign the AEFI form in the space provided and specify your professional status (e.g., Medical doctor [MD]; Registered nurse [RN]) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.

Please also provide the dates when the event was reported to the service provider and when it was reported to the local PHO.

Section 8: AEFI details

Indicate the details of the reported AEFI by checking all that apply. All additional pertinent details (e.g., associated fever, medical investigation, treatment, etc.) should be provided in Section 9. For convenience and consistency, high level definitions have been provided for most events listed in Section 8. However, if an asterisk (*) is present beside an AEFI term, this specific event **must be diagnosed by a physician** and thus a corresponding definition has not been provided within the body of this document.

Please refer to Appendix III for the summary of reporting criteria.

Section 8a: Local reaction around injection site

Please indicate the onset date and time of the first symptom or sign.

Choose from Section 8a all local reactions at or near the injection site that best fit the AEFI being reported: ***infected abscess, sterile abscess, cellulitis, nodule, reaction that crosses joint, lymphadenitis or other.***

For any injection site reaction indicated above, describe the signs and symptoms by checking all that apply: ***swelling***, ***pain***, ***tenderness***, ***erythema***, ***warmth, induration***, ***rash***, ***largest diameter of injection site reaction, site(s) of reaction***, ***palpable fluctuance, fluid collection shown by imaging technique***, ***spontaneous/surgical drainage***, ***microbial results, lymphangitic streaking***, ***regional lymphadenopathy.***

Please refer to Appendix III for the summary of reporting criteria.

Section 8b: Allergic and allergic-like events

Please indicate the onset date and time of the first symptom or sign.

Choose from Section 8b one of the following: ***Anaphylaxis, Other allergic events or Oculo-Respiratory Syndrome (ORS).***

For a chosen event, indicate the affected body system (***skin-mucosal, cardio-vascular, respiratory, gastrointestinal***) and the associated sign(s) and symptom(s) – choosing all that apply.

Provide all additional details in Section 9, including the measured pulse and blood pressure when available. Also, provide comment regarding whether there is visible swelling of the face (e.g., lips, tongue, uvula, etc.) and if a hoarse voice is audible to the reporter.

Please refer to Appendix III for the summary of reporting criteria.

Section 8c: Neurologic events

Please indicate the onset date and time of the first symptom or sign.

Choose from Section 8c all that apply neurologic events: ***meningitis, encephalopathy/encephalitis, Guillain-Barré syndrome (GBS), Bell's palsy, other paralysis, seizure(s), other neurologic diagnosis.***

For neurologic event chosen above, indicate all that apply signs, symptoms, details and test results.

Provide all additional details in Section 9. Please refer to Appendix III for the summary of reporting criteria.

Section 8d: Other defined events of interest

Please indicate the onset date and time of the first symptom or sign.

Choose from Section 8d all defined events of interest that apply to reported AEFI: ***hypotonic-hyporesponsive episode, persistent crying, intussusception, arthritis, parotitis, rash, thrombocytopenia, aneasthesia/paresthesia, fever, other serious or unusual/unexpected events not listed elsewhere on the form.***

For events chosen above, indicate all that apply signs, symptoms, details and test results.

Provide all additional details in Section 9. Please refer to Appendix III for the summary of reporting criteria.

Section 9: Supplementary information

Section 9 should be used to capture information pertinent to the AEFI but that has not been fully captured elsewhere on the form or that needs further explanation. Document all known details of investigations that support or refute the event(s), treatments, course of the event(s), and diagnosis for the recorded AEFI. The narrative should serve as a comprehensive, stand-alone "medical story." The information should be presented in a logical time sequence; ideally this should be presented in the chronology of the client's experience, rather than in the chronology in which the information was received. In follow-up reports, new information should be clearly identified. Also, indicate the section of the AEFI report that the information applies to, if applicable, when recording information in Section 9.

Abbreviations and acronyms should be avoided, with the possible exception of laboratory parameters and units. Key information from supplementary records should be included in the report, and their availability should be mentioned in the narrative and supplied on request.

Section 10: Recommendations for future vaccination

This section is to be completed by the MOH or his or her designate that provides recommendation(s) for further immunization(s).

Indicate, by choosing all that apply in Section 10, your recommendations for the client with regard to future vaccinations and specify additional information when requested. A comments section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in Section 9.

Complete the MOH's or his or her designate information section in full providing your full name and professional status (Medical Officer of Health [MOH]; Public Health Nurse [PHN]). In addition, indicate a telephone number where you can be reached and sign and date the AEFI form in the space provided.

5 APPENDIX I: NB AEFI REPORTING FORM

New Nouveau Brunswick

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) REPORT FORM

INSTRUCTIONS:

Please complete this form to report events that are **serious** OR **require an urgent medical attention** OR **unusual/unexpected** AND have a temporal association with a vaccine and that cannot be clearly attributed to other causes.
A causal relationship does not need to be proven, and submitting a report does not imply causality.

Please indicate what type of event is reported with an "√":

- ❑ **Serious** (*death, life-threatening, hospitalization, disability, congenital anomaly, medically important)*
- ❑ **Require an urgent medical attention** *(not resulted in hospitalization)*
- ❑ **Unusual or unexpected** *(not consistent with product information / labeling);* regardless of its severity

An AEFI is a reportable event in New Brunswick and should be reported to a Medical Officer of Health in writing **within one week of identification** (Public Health Act- Charter P-22.4; New Brunswick regulation 2009-141).

NOTE: ***The numbers below correspond to the numbered sections of the form.***
Please indicate if this report is initial or follow up (top right corner of the 1st page of the form)

1. The "Province case #" will be completed by the CDC Unit at the OCMOH.
2. The information provided in this section is confidential. Only *First Initial* of the first and last names, *Date of Birth*, *Gender*, *City/town* and *Postal Code* should be sent to the CDC Unit. Please block all other personal information prior to sending the form to the CDC Unit.
6. Provide details of level of care obtained, outcome and all investigations in section 9. If client had recovered at the time of reporting, provide the date. If the reaction lasted >1 hour, but <1 day also provide the exact time of recovery. For all hospitalizations, indicate the date of admission and discharge.
8. Choose, from section 8 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the onset date and time of the 1st symptom or sign.
9. Use section 9 to provide all additional details relevant to the event, duration of all symptoms, comments and other information as appropriate.
10. This section is to be completed by the MOH or their designate who provides public health recommendations.
    MOH: Medical Officer of Health; MD: Medical Doctor; PHN: Public Health Nurse.

Any item marked on the form with asterisk (*) must be diagnosed by a physician.

For more complete instructions and definitions, refer to the AEFI report form user guide at:
http://www.phac-aspc.gc.ca/im/aefi_guide/index-eng.php

Return the completed form to your local Public Health Office:

Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7
Moncton 81 Albert Street, PO Box 5001, NB, E1C 8R3 T: 506-856-2401 F: 506-856-2623	**Saint John** 55 Union Street, PO Box 93, NB, E2L 3X1 T: 506-658-5188 F: 506-643-7894	**Fredericton**, 300 St. Mary's Street, Room 11, NB, E3B 5H1 T: 506-453-5200 F: 506-444-4877	**Edmundston** 121 Church St., Suite 330, NB, E3V 3L3 T: 506-735-2065 F: 506-735-3142	**Campbellton** 6 Arran Street, 1st Floor, NB, E3N 1K4 T: 506-789-2266 F: 506-789-2349	**Tracadie-Sheila** 3520 Main Street, Place Tracadie NB, E1X 1C9 T: 506-394-3888 F: 506-394-3858	**Miramichi** 1780 Water St, Suite 300, NB, E1N 1B6 T: 506-778-6104 F: 506-778-6756

For local Public Health Office use only:

Please fax the completed form to **(506) 453-8702** to the attention of the CDC Unit Epidemiologist

Canada

November 2010

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New Nouveau Brunswick

❑ Initial report
❑ Follow up report

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1. Province case #:

2. Client Identification

First name:	Last name:	Medicare number:	**Date of birth:** YYYY / MM / DD **Sex:** ❑ Male ❑ Female
Address of residence:	**City/Town:**	**Postal code:**	Phone #:

Information source Name: Relation to client:

Contact info, if different:

Name of client's physician: Address: Phone #:

3. Vaccine Information **Province of Immunization:** _____ **Date vaccine administered:** YYYY / MM / DD (hr: am/pm)

Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		

4. Immunization Errors

Did this AEFI follow an incorrect immunization? ○ **Yes** ○ No ○ Unknown
(If **Yes,** *choose all that apply and provide detail in section 9)*
❑ Given outside the recommended age limits ❑ Product expired ❑ Wrong dose
❑ Wrong vaccine given ❑ Incorrect route ❑ Other, *specify:*

5. Previous AEFI

Did an AEFI follow a previous dose of any of the above immunizing agents?
○ No ○ **Yes** *(Provide details in section 9)*
○ Unknown ○ Not applicable (no prior doses)

6. Level of care and outcome *(Provide details in section 9)*

6a. Highest level of care obtained:
❑ Unknown ❑ None ❑ Telephone advice from a health professional
❑ Non-urgent visit ❑ Emergency visit
❑ Required hospitalization: ○ **Yes** ○ No
Date of hospital admission YYYY / MM / DD
Date of hospital discharge YYYY / MM / DD

6b. Outcome at time of report:
❑ *Death Date: YYYY / MM / DD ❑ Unknown
❑ *Not yet recovered ❑ *Permanent disability/incapacity
❑ Recovered Date: YYYY / MM / DD (hr: am/pm)
*(Provide details in section 9 for items with *)*

6c. Treatment received: ○ **Yes** *(If yes, provide details below)* ○ No ○ Unknown

6d. Medical history (up to the time of AEFI onset) *(Choose all that apply and provide details below or enclose a print out)*
❑ Concomitant medication(s) ❑ Known medical conditions/allergies ❑ Acute illness/injury

7. Reporter Information

Setting : ○ Physician office ○ Public Health ○ Hospital ○ Pharmacy ○ Other, *specify:*_____
Name: **Phone:** ( ) - (ext:) Fax: ( ) -
Address: **Date reported to Service Provider:** YYYY / MM / DD
City: Province: Postal code: **Date reported to Public Health:** YYYY / MM / DD
Signature: _____ ○ MD ○ RN ○ Other, *specify:*_____

Canada

Note: Discuss with client or his/her parent/caregiver reason for reporting and confidentiality of information 2

Province case #:

8. AEFI Details: *for each section check all signs/symptoms that apply. Use section 9 to provide clinical details and test results.*
Any item marked with asterisk (*) must be diagnosed by a physician.

❑ 8a. LOCAL REACTION around injection site — **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

❑ Infected abscess ❑ Sterile abscess ❑ Cellulitis ❑ Nodule ❑ Reaction crosses joint ❑ Lymphadenitis ❑ Other, *specify:*

For any injection site reaction indicated above, check all that apply below and provide details in section 9

❑ Swelling ❑ Pain ❑ Tenderness ❑ Erythema ❑ Warmth ❑ Induration ❑ Rash ❑ Largest diameter of injection site reaction: ____ cm

Site(s) of reaction _____ (e.g. LA, RA) ❑ Palpable fluctuance ❑ Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)

❑ Spontaneous/surgical drainage ❑ Microbial results ❑ Lymphangitic streaking ❑ Regional lymphadenopathy

❑ 8b. ALLERGIC and ALLERGIC-LIKE EVENTS — **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

Chose one of the following: ❑ ***Anaphylaxis** ❑ **Other allergic events** ❑ **Oculo-Respiratory Syndrome (ORS)**

For a chosen event, check all that apply below and provide details in section 9

Skin /mucosal	❑ Urticaria ❑ Erythema ❑ Pruritus ❑ Prickle sensation ❑ Rash *(For these events, specify site of reaction)*	
	ANGIOEDEMA: ❑ Tongue ❑ Throat ❑ Uvula ❑ Larynx ❑ Lip ❑ Eyelids ❑ Face ❑ Limbs ❑ Other, *specify:*	EYE(S): ❑ Red bilateral ❑ Red unilateral ❑ Itchy
Cardio-vascular	❑ Measured hypotension ❑ ↓central pulse volume ❑ Capillary refill time >3 sec ❑ Tachycardia ❑ ↓ or loss of consciousness (*Duration*) _____	
Respiratory	❑ Sneezing ❑ Rhinorrhea ❑ Hoarse voice ❑ Sensation of throat closure ❑ Stridor ❑ Dry cough ❑ Tachypnea ❑ Wheezing ❑ Indrawing/retractions ❑ Grunting ❑ Cyanosis ❑ Sore throat ❑ Difficulty swallowing ❑ Difficulty breathing ❑ Chest tightness	
Gastrointestinal	❑ Diarrhoea ❑ Abdominal pain ❑ Nausea ❑ Vomiting	

❑ 8c. NEUROLOGIC EVENTS — **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

❑ ***Meningitis** ❑ ***Encephalopathy/Encephalitis** ❑ ***Guillain-Barre Syndrome (GBS)** ❑ ***Bell's Palsy** ❑ ***Other Paralysis**
❑ **Seizure** ❑ ***Other neurologic diagnosis,** *specify:*

For any neurologic event indicated above, check all that apply below and provide details in section 9

❑ Depressed/altered level of consciousness, lethargy or personality change lasting ≥24hrs ❑ Focal or multifocal neurologic sign(s)
❑ Fever (≥ 38.0^{0}C) ❑ CSF abnormality ❑ EEG abnormality ❑ EMG abnormality
❑ Neuroimaging abnormality ❑ Brain/spinal cord histopathologic abnormality

Seizure details: ❑ Witnessed by healthcare professional: O Yes O No O Unknown
❑ Sudden loss of consciousness: O Yes O No O Unknown
❑ Focal **OR** ❑ Generalized (*Specify*: O Tonic O Clonic O Tonic-Clonic O Atonic)
❑ Previous history of seizures (*Specify*: O Febrile O Afebrile O Unknown type)

❑ 8d. OTHER DEFINED EVENTS OF INTEREST — **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

For all selected defined events of interest below, provide details in section 9

❑ Hypotonic-Hyporesponsive Episode (age <2 years): ❑ Limpness ❑ Pallor/cyanosis ❑ ↓responsiveness/unresponsiveness	**❑ *Thrombocytopenia:** ❑ Platelet count <150x10^9/L ❑ Petechial rash ❑ Other clinical evidence of bleeding
❑ Persistent crying (*Crying which is continuous and unaltered for ≥ 3h*)	**❑ Anaesthesia/Paraesthesia** (❑ Numbness ❑ Tingling ❑ Burning ❑ Formication ❑ Other, *specify:*) ❑ Generalized **OR** ❑ Localized (*Site*) _____
❑ *Intussusception	
❑ Arthritis: ❑ Joint redness ❑ Joint warm to touch ❑ Joint swelling ❑ Inflammatory changes in synovial fluid	**❑ Fever ≥38.0^{0}C** *(Note: report ONLY if fever occurs in conjunction with a reportable event. For fever in a neurological event, use section 8c)*
❑ Parotitis *(Parotid gland swelling with pain and/or tenderness)*	**❑ Other serious or unusual/unexpected event(s) not listed elsewhere on the form** 3
❑ Rash (*Non-allergic*): ❑ Generalized ❑ Localized (site)_____	

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9. Supplementary information *(Please indicate the section # when providing details; please provide details of any investigation or treatment for the recorded AEFI).*

For local Public Health Office use only:

10. Recommendations for future immunizations *(check all that apply below and provide comments in section 9 if extra space is needed)*

❑ No change to immunization schedule ❑ Expert referral, *specify:* ❑ Determine protective antibody level	❑ Controlled setting for next immunization ❑ No further immunizations with, *specify:* ❑ Active follow-up for AEFI recurrence after next vaccine	❑ Other, *specify:*

Name: Professional status: O MOH O PHN O Other, *specify:*_____

Comments:

Phone: ( ) - (ext:) **Date:** YYYY / MM / DD **Signature**: _____

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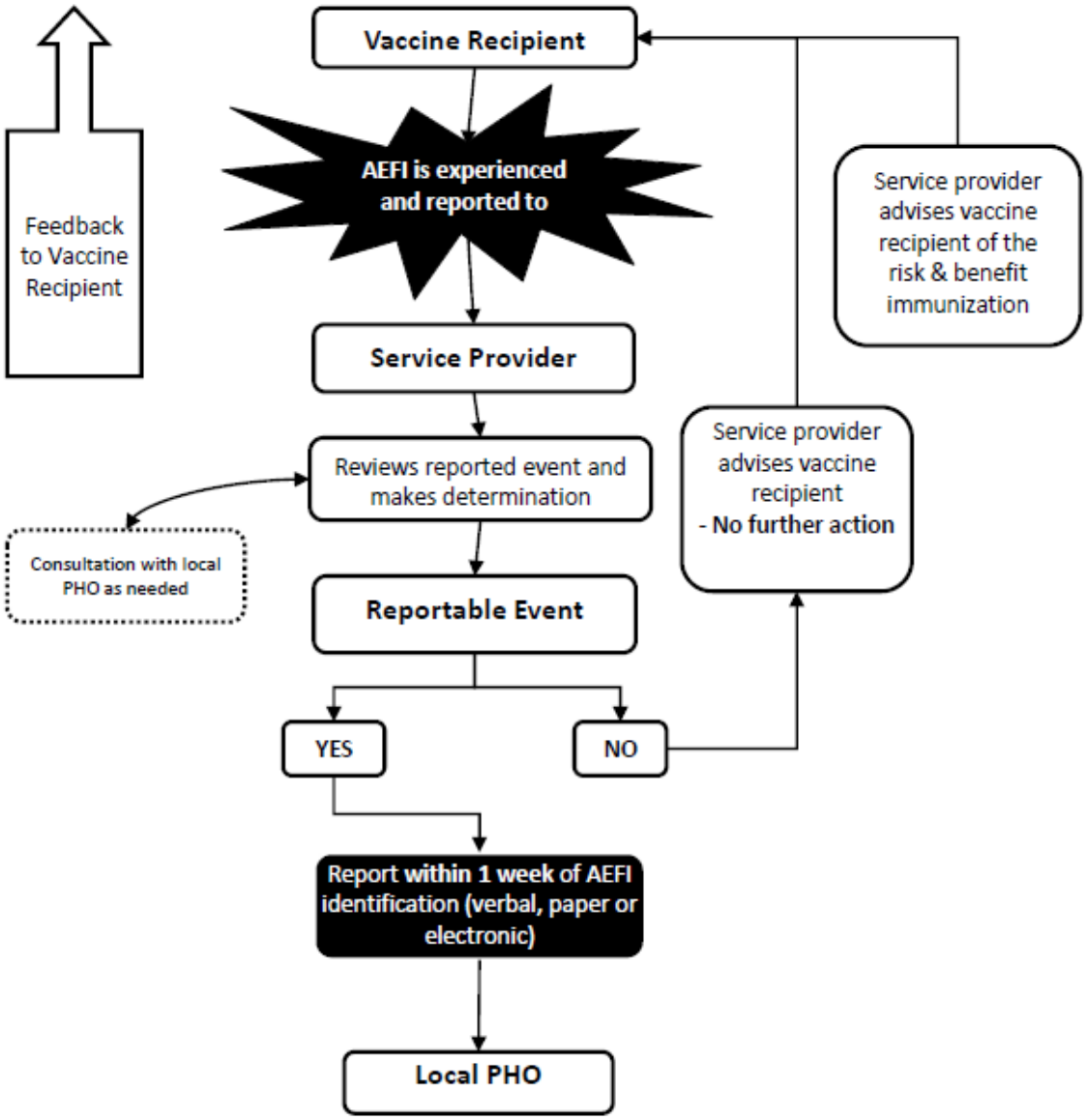
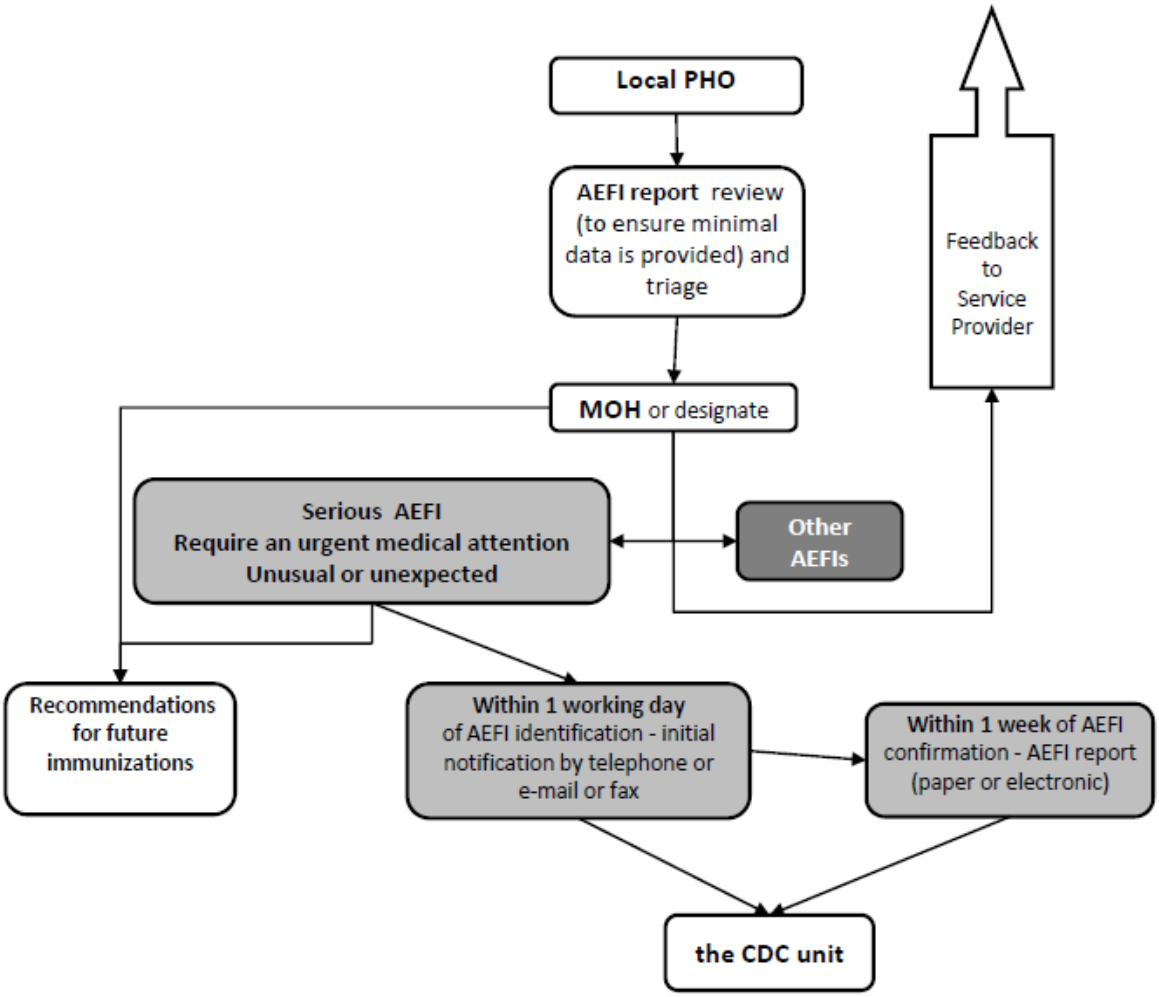
6 APPENDIX II: AEFI REPORTING FLOWCHART

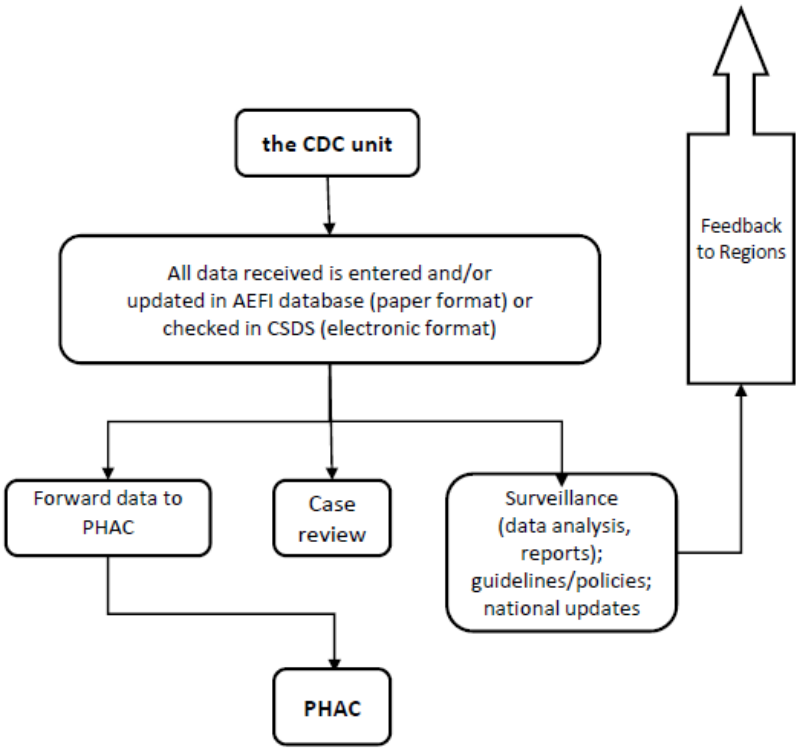
Service provider/Local level


Vaccine Recipient
AEFI is experienced and reported to
Feedback to Vaccine Recipient
Service provider advises vaccine recipient of the risk & benefit immunization
Service Provider
Reviews reported event and makes determination
Consultation with local PHO as needed
Service provider advises vaccine recipient
- No further action
Reportable Event
YES
NO
Report within 1 week of AEFI identification (verbal, paper or electronic)
Local PHO

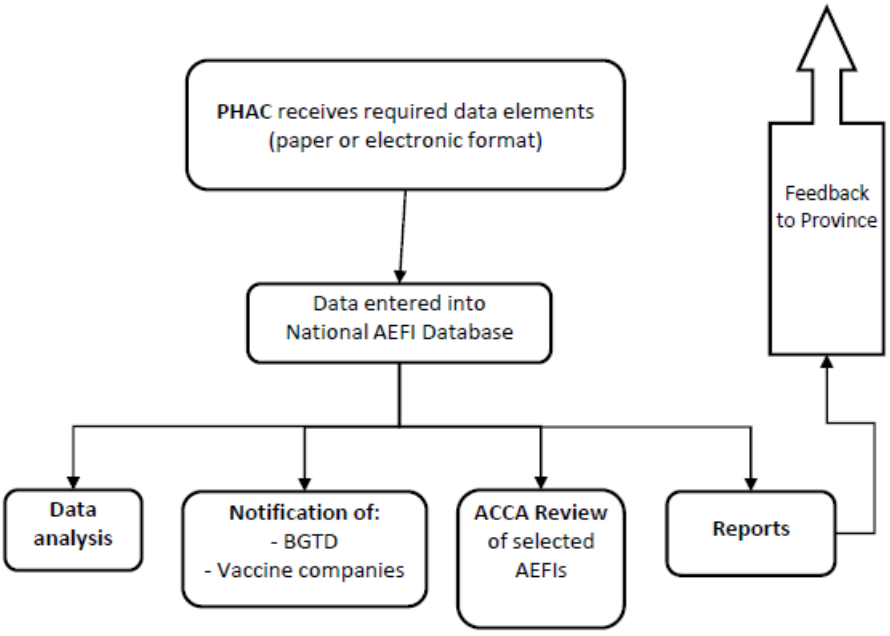
Regional level


Local PHO
AEFI report review (to ensure minimal data is provided) and triage
Feedback to Service Provider
MOH or designate
Serious AEFI
Require an urgent medical attention
Unusual or unexpected
Other AEFIs
Recommendations for future immunizations
Within 1 working day of AEFI identification - initial notification by telephone or e-mail or fax
Within 1 week of AEFI confirmation - AEFI report (paper or electronic)
the CDC unit

Provincial level


the CDC unit
All data received is entered and/or updated in AEFI database (paper format) or checked in CSDS (electronic format)
Forward data to PHAC
Case review
Surveillance (data analysis, reports); guidelines/policies; national updates
PHAC
Feedback to Regions

Federal level


PHAC receives required data elements (paper or electronic format)
Data entered into National AEFI Database
Data analysis
Notification of: - BGTD - Vaccine companies
ACCA Review of selected AEFIs
Reports
Feedback to Province

7 APPENDIX III: SUMMARY OF REPORTING CRITERIA

*The length of time between vaccine administration and onset of symptoms is an important consideration in causality assessment. Temporal criteria listed below are approximate timelines of which an applicable AEFI could occur.

AEFI	Reporting criteria	*Vaccines (temporal criteria)	
		Inactivated	Live attenuated
LOCAL REACTION AT INJECTION SITE			
Minor reactions	• Redness or swelling or pain extends past the nearest joint AND/OR • Redness or swelling or pain persists for 10 days of more	0-48 hours	0-48 hours
Major reactions: Arthus reaction	• Onset within 48 hours of immunization AND • Swelling extends past the nearest joint	0-48 hours	0-48 hours
Infected abscess	• Physician diagnosed AND • Material from the abscess is purulent (positive gram stain or culture) OR • Signs of localized inflammation (erythema, pain to touch, warmth) AND • Evidence of improvement with antimicrobial therapy	0-7 days	0-7 days
Sterile abscess	• Persists for >1 month, is >2.5cm in diameter and/or drainage is evident AND • Material from the mass is non-purulent AND • Absence of localized inflammation OR • Failure to improve on antimicrobial therapy	0-7 days	0-7 days
Nodule	• Is >2.5cm in diameter • Persists for >1 month	0-7 days	0-7 days
Cellulitis	• Physician diagnosed AND • Characterized by at least 3 local signs or symptoms: pain or tenderness to touch, erythema, induration or swelling, warmth to touch	0-7 days	0-7 days

SYSTEMIC EVENTS			
Fever	• Fever that occurs in conjunction with another reportable event	0-72 hours	0-42 days
Rash	• Generalized rash for which urgent medical attention is sought and believed to be related to vaccine • Any rash requiring hospitalization or treatment in ER	0-7 days	5-26 days
Adenopathy/ lymphadenopathy	• Enlargement of one or more lymph nodes, ≥1.5cm in diameter AND/OR • Draining sinus over a lymph node	0-6 days	1-6 months
HHE	• Physician diagnosed AND • Reduced muscle tone AND • Hyporesponsiveness AND • Pallor or cyanosis AND • Child <2 years of age	0-48 hours	0-48 hours
Screaming/ Persistent crying	• Continuous, unaltered crying lasting for 3 or more hours	0-72 hours	0-72 hours
Parotitis/ Orchitis	• Physician diagnosed following immunization with mumps-containing vaccine		5-30 days
Vomiting/ Diarrhea	• 3 or more episodes in 24-hour period AND • Severe (i.e. projectile vomiting or explosive, watery diarrhea)	0-72 hours	0-72 hours
ALLERGIC REACTIONS			
Allergic reactions	• Any allergic reaction (hives, bronchospasm, edema) occurring within 72 hours of immunization	0-48 hours	0-48 hours
Anaphylaxis	• All adverse events managed as anaphylaxis at the time of occurrence	0-24 hours	0-24 hours
ORS	• Bilateral red eyes and respiratory symptoms with onset within 24 hours of Influenza vaccine receipt	Influenza: 0-24 hours	
NEUROLOGIC EVENTS			
Convulsion/ seizure	• Seizures (febrile or afebrile) if they meet the temporal criteria	0-3 days	5-42 days
Encephalopathy/ encephalitis	• Physician diagnosed encephalopathy or encephalitis	0-15 days	2-42 days

Meningitis	• Physician diagnosed meningitis for which no other cause was identified	0-15 days	2-42 days
Anesthesia/ paresthesia	• Physician diagnosed anesthesia or paresthesia lasting 24 hours or more	0-7 days	0-7 days
Paralysis	• Physician diagnosed paralysis lasting 24 hours or more	0-15 days	0-42 days
GBS	• Physician diagnosed GBS	0-8 weeks	0-3 months
Bell's palsy	• Physician diagnosed Bell's palsy	0-8 weeks	0-3 months
SSPE	• Physician diagnosed SSPE		
MISCELLANEOUS			
Thrombocytopenia	• Physician diagnosed occurring within 30 days post-immunization	0-30 days	0-30 days
Arthralgia/Arthritis	• Any arthralgia or arthritis that follows the receipt of rubella-containing vaccine and lasting at least 24 hours		0-42 days
Intussusception	• Intussusception or Hematochezia following rotavirus vaccine receipt		0-42 days
Syncope with injury	• Any syncope with injury following immunization	0-24 hours	0-24 hours
Death	• Any death of a vaccine recipient temporally linked to immunization where no other clear cause of death can be established	Within 1 month	Within 1 month
Fetal death or abnormality	• Any fetal death or abnormality that follows immunization of a pregnant woman		